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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION TWO

AUDREY TIMMIS, et al., Plaintiffs and Appellants, v. KAISER PERMANENTE, et al. Defendants and Respondents.	A102962 (Alameda County Super. Ct. No. 833971-7)

I. INTRODUCTION

Respondents Kaiser Permanente, Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals, Inc., and the Permanente Medical Group, Inc. (Kaiser Permanente)[1] operate a health maintenance organization (HMO). Relying primarily on California's Unfair Competition Law, Business and Profession Code section 17200 et seq. (the UCL), appellants seek to enjoin Kaiser Permanente to discontinue or substantially modify a policy relating to its provision of prescription drug benefits to its patient members. The trial court granted Kaiser Permanente summary judgment. We affirm, albeit on different bases than used by the trial court.

[1] According to respondents, "Kaiser Permanente" is the trade name for the "integrated heath care delivery system" comprised of Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals, Inc., and the Permanente Medical Group, Inc. Therefore, we refer to the group of respondents as Kaiser Permanente.

II. STATEMENT OF FACTS

A. *Appellants' Claims*

Several current and former patients of Kaiser Permanente, a doctor previously employed by Kaiser Permanente, and a patient advocacy group (jointly appellants) filed this action in December 2000. In a first amended complaint filed April 27, 2001, appellants alleged that Kaiser Permanente's pharmacy and drug prescription program violates the UCL and the Consumers Legal Remedies Act, Civil Code section 1770 (the CLRA). Specifically, appellants challenged the legality of a "pill-splitting program" they claim Kaiser Permanente has adopted. According to the allegations in the first amended complaint, Kaiser Permanente "forces its out-patient members—many of whom are elderly and infirm—to accept prescribed medication in dosages twice the amount necessary for a single dose and requires them to split the pills in half in order to obtain their prescribed dosages."

In their first cause of action, appellants alleged that Kaiser Permanente's pill splitting program violates the UCL because it (1) subjects patients to inconvenience and "potential physical injury" by forcing them to engage in pill-splitting of unscored pills solely for the purpose of increasing Kaiser's revenues; and (2) requires patients to split both scored and unscored pills without disclosing the potential risks of such a practice and without ensuring either that patients are capable of properly splitting their medication or that patients are actually obtaining the prescribed dosage without suffering inconvenience or other adverse effect. Appellants also alleged that this pill splitting program is inconsistent with representations Kaiser Permanente makes about "the quality of medical care and services" it provides and with representations it makes to consumers that only doctors and patients make medical decisions when, "in fact, neither doctors nor patients can override the pharmacy policy requiring that medication be dispensed in double-doses and be split for use by the patient . . . ." In a second causes of action, appellants alleged that statements Kaiser Permanente makes to the public about the quality of the medical care it affords constitute fraudulent and misleading advertising in violation of the section 17500 of the UCL.

The first amended complaint also contains a third cause of action alleged only by those appellants who are former or current patients of Kaiser Permanente. These appellants alleged that misrepresentations Kaiser Permanente makes about the quality of the services it provides and about who makes medical decisions on behalf of patients constitute violations of the CLRA. This cause of action is alleged as a class action on behalf of similarly situated current or former Kaiser patients. In contrast to the first two causes of action, which seek only restitution and injunctive relief, the third cause of action contains a demand for actual damages, penalties pursuant to section 1780, subdivision (b), of the Civil Code, and punitive damages. The trial court found that the damages claim alleged in this cause of action was subject to arbitration. It severed that part of the CLRA claim and stayed the arbitration pending resolution of appellants' equitable claims under the UCL and the CLRA.

Appellants have not alleged that Kaiser Permanente's pill-splitting policies caused any individual to suffer actual physical injury. Indeed, in response to discovery requests, those appellants who are or were members of Kaiser Permanente conceded their claims "do not relate to any personal injuries received as a result of pill splitting." Further, after appellants refused to produce medical records sought during discovery, the trial court issued an order precluding appellants from "introducing any specific claims for personal injury, including but not limited to pain and suffering."

B. ***Kaiser Permanente's Policies Pertaining to Tablet Splitting***

Kaiser Permanente maintains, and appellants do not dispute, that tablet splitting for clinical reasons has been an accepted and sometimes necessary practice for many years. Kaiser Permanente also contends that, in recent years, health care providers have begun to utilize tablet splitting as a cost reduction measure. It is this practice to which appellants object.

Kaiser Permanente first began to develop tablet splitting initiatives for certain medications as part of a cost reduction strategy in the early 1990's. In 1999, its Regional Pharmacy and Therapeutics Committees in Northern and Southern California adopted written "Guidelines For the Selection Of Drugs/Tablets For Tablet Splitting Initiatives"

(the Guidelines). The Guidelines divide into two parts, a "Background" section and a list of "Criteria" for selecting drugs suitable for a tablet splitting initiative.

The Background section states: "Tablet splitting has been used for many years as a method to obtain a prescribed dose of a medication when it is not commercially available. This has been particularly useful for pediatric dosing. More recently, tablet splitting has been used as a cost reduction strategy. In many cases, different strength tablets of the same medication are priced equally. By splitting a tablet that is twice the strength of the dose desired, the cost to the patient can be halved.[**2**] [¶] Many tablets are manufactured with a score across the tablet making it easy to halve. Other tablets are not scored or are available in varying sizes and shapes. These guidelines are intended to address tablets that are not scored by the manufacturer. Before a tablet is recommended as a candidate to be split for cost reduction purposes, it must meet certain criteria. Factors which are considered include the pharmacodynamics of the drug; the ease with which the tablets can be split consistently into equal units; the disease being treated; acceptance by the medical group; and the ability (cognitively and physically) and acceptance of the patient to split tablets."

The first two criteria set forth in the Guidelines describe the general characteristics of drugs which are and are not suitable for tablet splitting. Drugs suitable for tablet splitting should have a "wide therapeutic window and low-medium intrasubject variability." However, tablets which should not be split include hydroscopic drugs which are coated to protect from moisture, enteric-coated tablets and controlled release tablets. The third criterion describes the type of data that will support selection of a drug for a tablet splitting initiative. Such data includes clinical data, pharmacokinetic data, and weight variation testing.

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2 One example set forth in the record pertains to the antidepressant Paxil. A patient requiring a 10-milligram daily dose of this medication would pay $2.19 a day to take a 10-milligram tablet. However, since a 20-milligram tablet also costs $2.19, splitting the 20-milligram tablet to achieve a 10-mg does lowers the daily cost to $1.10, a savings of 50%.

The fourth criterion in the Guidelines calls for approval at various levels. Once a drug is approved for tablet splitting by the Pharmacy and Therapeutics Committee and physician specialty groups, if appropriate, a specific provider can determine that a specific patient is not an appropriate candidate for tablet splitting. Further, the Guidelines expressly state that "[a]ny patient or patient's caregiver has the right to refuse to split tablets with impunity."

The final two criteria underscore the limited purpose of the Guidelines. The fifth criterion pertains to monitoring and advises that providers should monitor patients according to their clinical judgment and should report any problems they encounter with the tablet splitting program. The final criterion pertains to "other tablets" not selected for a tablet splitting initiative and states that the Guidelines do not "preclude prescribing of half tablets of other medications as deemed clinically appropriate by any physician or prescriber."

An Addendum to the Guidelines includes a list of seven drugs that have been approved for tablet splitting and four additional drugs that have been tested for tablet splitting. A "Note" associated with these lists reiterates that the Guidelines do not preclude the prescribing of half tablets of other medications as deemed clinically appropriate by any physician or prescriber.

Mirta Millares is the Manager of Drug Information Services and Pharmacy Outcomes Research for Kaiser Foundation Health Plan, Inc. and is familiar with the development of Kaiser Permanente's pharmaceutical programs including the use of tablet splitting programs and policies. According to a declaration by Millares, each of the seven medications that are currently subject to regional tablet splitting initiatives in California was selected by applying the Guidelines and the judgment of the physicians and pharmacists on the Regional Pharmacy and Therapeutic Committees.[3] Millares also stated that, even after the determination has been made that a medication is appropriate

[3] These committees are comprised of physicians and pharmacists although only one pharmacist is a voting member.

for tablet splitting, the individual physician determines whether tablet splitting is appropriate for his or her patient and that a member who receives tablets that must be split is provided with a "tablet splitter" along with his or her prescription.

The record contains declarations by two current members of the Kaiser Health Plan who are not parties to this action. Both men stated that they have been instructed to split pills prescribed to them by a Kaiser physician. Both men, and their wives who submitted separate declarations, claimed they were not told that they could refuse to split tablets, they were not instructed by a doctor or pharmacist as to how to properly split tablets, and nobody followed-up to ensure that they were properly splitting the pills or whether taking the medication in this fashion had an adverse effect on them. One of the declarants had been prescribed sildenafil (Viagra) which is on Kaiser Permanente's list of approved drugs for tablet splitting. The other declarant had been prescribed Coumadin, which is not on that list and which has never been included in a pill-splitting initiative adopted by Kaiser Permanente. However, Millares stated in her declaration that it is a common practice for prescribers to have patients split this medication to obtain a desired dosage. Millares underscored that physicians or other prescribers employed by Kaiser Permanente may independently determine that a partial tablet is appropriate to achieve and intended dose for an individual patient and that such a determination is within the sole purview of the provider; it need not be justified by a tablet splitting initiative and does not require any other approval.

C. ***Agency Involvement and Investigations***

In March 1999, before this action was filed, appellant Charles Phillips, M.D., sent a letter to the federal Food and Drug Administration (FDA) complaining about Kaiser Permanente's pill splitting policies. Celia DeLawter, Executive Secretariat for the Center for Drug Evaluation and Research, responded to Phillips's complaint. In a letter dated April 15, 1999, DeLawter advised Phillips that "[t]he practice of pharmacy is regulated by individual state agencies," and she suggested that Phillips contact the State Board of Pharmacy. In response to subsequent correspondence from Phillips regarding this matter, DeLawter stated: "How a doctor prescribes a medication for patient use is considered the

practice of medicine. The Food, Drug, and Cosmetic Act does not provide the Food and Drug Administration (FDA) with authority to regulate the practice of medicine." DeLawter also suggested Phillips share his concern with the Health Care Finance Administration, the agency that administers the Medicare and Medicaid programs.

In February 2000, the California Board of Pharmacy sent a letter to Kaiser Permanente indicating it was investigating a complaint regarding Kaiser Permanente's tablet splitting policies.[4] The Board requested that Kaiser Permanente produce a copy of its policy regarding pill splitting and a "legal justification" for that policy. Kaiser Permanente provided the requested information to the Pharmacy Board on February 22, 2000.

The California Department of Managed Health Care also initiated an investigation concerning Kaiser Permanente's tablet splitting policies. In March 2001, the Department issued a subpoena seeking documents relating to these policies in "In the Matter of the Investigation and Examination of Kaiser Foundation Health Plan, Inc." Kaiser Permanente responded to the subpoena in May 2001.

D. ***Expert Evidence***

Helene Lipton is a professor of Pharmacy and Health Policy at UCSF. According to Lipton's declaration, the rising costs of prescription drugs poses significant problems to patients, insurers and health care providers. She attributes these rising costs to a variety of factors including increased demand, increased availability due to increased enrollment in managed care plans that afford prescription benefits, and drug price inflation. She further opines that health maintenance organizations have responded to this problem by either withdrawing prescription benefits or by adopting price controls like the tablet splitting policy at issue in this case.

According to Lipton, tablet splitting is a "promising tool" for providing cost-effective pharmacy services and it has been utilized by many major health care systems including local and regional VA programs, Medicaid programs, the Department of

[4] Phillips complained to the Board of Pharmacy and other agencies as well.

Defense and Group Health Cooperative of Puget Sound. Lipton reviewed the tablet splitting programs used by Medicaid programs in Iowa, Minnesota and Nebraska, and by the Medi-Cal program in Orange County as well as by an unidentified West-Coast based nonprofit, integrated health care system. According to Lipton, most of these tablet splitting programs are mandatory, with exceptions that require prior approval, and there have been no reported problems with patient non-compliance, patient injuries or health risks.

Lipton also maintains that evidence from available studies of this practice (1) does not establish there is increased risks or decreased safety associated with splitting tablets; (2) suggests patients find the practice acceptable and that tablet splitting strategies can be implemented without affecting patent compliance and; (3) indicates tablet splitting reduces costs to both health care systems and to patients. Based on these and other considerations, Lipton opined that "[t]ools such as tablet splitting, used in conjunction with other innovative strategies, enables an organization such as Kaiser Foundation Health Plan, Inc. to preserve pharmacy benefits for its members, maximize members' abilities to realize fully the value of their allocated annual drug benefit, and advance public heath goals by providing better access to needed medicines."

Leslie Z. Benet, a professor of Biopharmaceutical Sciences at the University of California, San Francisco, School of Pharmacy, was retained to give an expert opinion regarding the propriety of the Guidelines themselves. It was Benet's opinion that Kaiser Permanente's Guidelines "set forth appropriate criteria for determining those drugs that may be properly subject to tablet splitting." Benet also considered the specific drugs that Kaiser Permanente currently approves for tablet splitting and the drugs that have been subject to tablet splitting in the past. Benet opines that "splitting these drugs will not result in variations in daily doses that are clinically significant."

James Haas is a physician, a Diplomate in the American Board of Psychiatry and Neurology and a Medical Examiner. According to Haas, Kaiser Permanente's pill-splitting policy is "inappropriate and unwise." The primary flaw in Kaiser's policy, according to Haas, is that it fails to assure adequate disclosure. Indeed, Haas offered the

opinion that, in order to comply with the standard of care and practice in California, Kaiser Permanente would have to disclose to patients that "regular, long-term pill-splitting has not been proven to be equally safe or effective as full-tablet dosing, and that it may, in fact, result in significantly less favorable clinical outcomes than full-tablet dosing; that there is no medical or clinical reason to engage in such a treatment plan and that the only purpose of the plan is to provide Kaiser with an economic advantage."

Neil Spingarn is an analytical chemist and pharmacologist who owns and operates an independent laboratory which, among other things, performs pharmacokinetic testing for pharmaceutical companies. While acknowledging that pill splitting can be necessary and appropriate for clinical reasons, Spingarn opines that Kaiser Permanente's pill splitting policy is "inappropriate and unwise." He identified several "flaws" in the policy including that (1) it applies only to unscored pills and offers patients no protection with respect to splitting of scored pills; (2) it does not require clinical studies to demonstrate that it is actually safe to have patients split the unscored pills approved for splitting; (3) there is no formal process for assuring that screening and training of patients actually occurs. Further, in Spingarn's opinion, the studies Kaiser Permanente relies on to justify its policy do not actually demonstrate that pill splitting is safe and the available studies demonstrate that this practice is not in fact safe for "a significant number of patients."

In his declaration, Spingarn stated that he is intimately familiar with the regulations and requirements of the FDA with respect to the approval of pharmaceuticals. According to Spingarn, in order for a manufacturer to obtain FDA approval of a pharmaceutical, it must produce information and test data for the specific "dosage form" it intends to produce and market. He maintains that a manufacturer would be "barred from producing 'split-dose' forms of medications absent the approval of the FDA based on extensive supporting studies, including safety studies." Thus, in Spingarn's view, Kaiser Permanente has side-stepped and undermined the careful regulatory system established by the FDA by adopting a program which puts "the onus on the patient to alter the approved forms of the drugs."

Peter Rheinstein is a medical doctor and lawyer currently employed at a biotechnology company specializing in cancer diagnostics and therapeutics. Between 1974 and 1999, Rheinstein held numerous positions at the FDA.[5] Rheinstein disagrees with the opinions expressed in Spingarn's declaration. According to Rheinstein, the Food, Drug and Cosmetic Act (FD&C Act) which the FDA administers applies to manufacturers not physicians: "The FDA's policy was and is that under the FD&C Act, a drug approved for marketing may be labeled, promoted and advertised by the manufacturer only for purposes for which the drug's safety and effectiveness have been approved by the FDA. However, the FD&C Act does not limit the manner in which a physician may use a prescribed drug. Once a drug and its labeling have been approved by the FDA, physicians may prescribe drugs for any uses that they believe are appropriate." Thus, Rheinstein maintains that Kaiser Permanente's tablet splitting policy does not violate, offend or circumvent the law enforced by the FDA.

E. ***The Summary Judgment Ruling***

Kaiser Permanente sought summary judgment on the grounds that (1) its "practice of encouraging tablet splitting" is not unlawful, unfair or fraudulent within the meaning of the UCL; (2) it did not make untrue or misleading statements or misrepresentations about tablet splitting or about the prescription drug benefits it provides which would support a finding of liability under the UCL or the CLRA; and (3) the court should deny relief under the doctrine of equitable abstention because all of the claims alleged "concern complicated issues of public healthcare policy and economics that should be

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[5] Rheinstein has served as the Director, Division of Drug Advertising and Labeling, Bureau of Drugs (1974-1982), Acting Director, Office of Drugs, National Center for Drugs and Biologics (1982-1983); Director, Office of Drug Standards, Center for Drug Evaluation and Research (1983-1990); and Director, Medicine Staff, Office of Health Affairs (1990-1999). In this last position, Rheinstein's responsibilities included "acting as the principal medical spokesperson for the FDA and interfacing with health professionals and their organizations and with other government health agencies." Rheinstein states that he is "fully familiar with the role and function of the FDA, as well as the laws that it is charged with administering in the area of prescription drugs."

determined by the Legislature and/or specific state regulatory agencies." Ultimately,[6] the court granted summary judgment on the third ground, judicial abstention.

III. DISCUSSION

The primary issue presented is whether the trial court erred by dismissing appellants' equitable claims. We also briefly address appellants' contention that the trial court erroneously granted Kaiser Permanente's motion to compel arbitration of the claim for damages under the CLRA.

A. *The Summary Judgment Ruling re the UCL and CLRA*

1. *Issue Presented and Standard of Review*

Although appellants attempted to allege numerous violations of the UCL, and were permitted to develop new theories of liability even in the midst of a summary judgment proceeding, they challenge one practice: Kaiser Permanente's tablet splitting policy. Their case is premised on the theory that the law should prohibit a managed care health services provider from employing a tablet splitting policy as a cost saving measure, allegedly at the risk to the health and safety of its subscribers. As noted above, the trial court concluded that a UCL action was not the proper vehicle for determining the lawfulness of this practice.

The trial court disposed of appellants' equitable claim under the CLRA as well. It did not independently address the merits of the CLRA claim but, instead, reasoned that appellants' CLRA theory, that Kaiser Permanente failed to disclose alleged risks relating to its tablet splitting policy, was inextricably intertwined with its UCL claim that those alleged risks rendered Kaiser Permanente's policy unfair and unlawful. Appellants do not challenge this aspect of the trial court's ruling. Indeed, they essentially ignore their CLRA claim (which, in any event, was never developed in the lower court) and do not

[6] For a variety of reasons, the court took a somewhat extended route to reach its grant of summary judgment. However, neither discussing those reasons nor retracing the court's route would be fruitful.

even dispute a statement in Kaiser Permanente's appellate brief that this claim has been abandoned. We will, therefore, focus our analysis on the UCL.[7]

"The trial court properly grants a motion for summary judgment 'if all the papers submitted show that there is no triable issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.' (Code Civ. Proc., § 437c, subd. (c).)" (*Mills v. Forestex Co.* (2003) 108 Cal.App.4th 625, 639.) "On appeal from a ruling on a motion for summary judgment, the appellate court conducts its own independent review of the moving and opposition papers and applies the same standard as the trial court in determining whether the motion was properly granted. The appellate court is not bound by the trial court's stated reasons for its ruling on the motion, as the appellate court reviews only the ruling and not its rationale. [Citation.]" (*Bed, Bath & Beyond of La Jolla, Inc. v. La Jolla Village Square Venture Partners* (1997) 52 Cal.App.4th 867, 873.)

2. *Guiding Principles*

The UCL does not proscribe specific practices but, instead, defines "unfair competition" to "include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1 (commencing with Section 17500) of Part 3 of Division 7 of the Business and Professions Code." (Bus. & Prof. Code, § 17200.) The scope of the UCL is broad: "Its coverage is 'sweeping, embracing "'anything that can properly be called a business practice and that at the same time is forbidden by law."'" [Citation.] It governs 'anti-competitive business practices' as well as injuries to consumers, and has as a major purpose 'the preservation of fair business competition.' [Citations.] By proscribing 'any unlawful' business practice, 'section 17200 "borrows" violations of other laws and treats them as unlawful practices' that the unfair competition law makes independently actionable. [Citations.]"

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[7] We note, however, that the trial court issued a tentative decision on the summary judgment motion in which it found that Kaiser Permanente was entitled to summary adjudication of the CLRA claim on the ground that appellants failed to produce any evidence of any affirmative misrepresentations about Kaiser Permanente's pharmacy policies. Our review of the record confirms this conclusion and thus provides an alternative basis for affirming summary judgment regarding the CLRA claim.

(*Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.* (1999) 20 Cal.4th 163, 180 (*Cel-Tech*).)

However, while the UCL's "scope is sweeping, it is not unlimited." (*Cel-Tech, supra*, 20 Cal.4th at p. 182.) For example, if the Legislature has permitted certain conduct or considered a situation and determined that no action will lie, a court cannot override or circumvent that "safe harbor" by finding the conduct actionable under the UCL. (*Cel-Tech, supra*, 20 Cal.4th at pp. 182-184; *Scripps Clinic v. Superior Court* (2003) 108 Cal.App.4th 917, 938 (*Scripps Clinic*.) Further, even when called upon to make an independent determination as to the fairness of a challenged practice, courts "may not simply impose their own notions of the day" or "apply purely subjective notions of fairness" in order to determine whether the challenged conduct is actionable under the UCL. (*Cel-Tech, supra,* 20 Cal.4th at pp. 182, 184.) Thus, for example, the UCL should not be used as a vehicle for determining "'the wisdom of any economic policy; that function rests solely with the legislature. . . .' [Citation.]" (*Cel-Tech, supra*, 20 Cal.4th at p. 184, quoting *Wolfe v. State Farm Fire & Casualty Ins. Co*. (1996) 46 Cal.App.4th 554, 562, and *Max Factor & Co. v. Kunsman* (1936) 5 Cal.2d 446, 454.)

In *Cel-Tech*, our Supreme Court undertook to "devise a more precise test for determining what is unfair" under the UCL and, more specifically, what was "unfair" in an UCL action brought by one competitor against another. (*Cel-Tech, supra,* 20 Cal.4th at p. 185.) It concluded that "to guide courts and the business community adequately and to promote consumer protection, we must require that any finding of unfairness to competitors under section 17200 be *tethered to some legislatively declared policy or proof of some actual or threatened impact on competition*." (*Id.* at pp. 186-187, emphasis added.)

The year after *Cel-Tech* was decided, this court noted the language just quoted and accepted "the suggestion of *Cel-Tech* that *any* claims of unfairness under the UCL should be defined in connection with a legislatively declared policy . . . ." (*Schnall v. Hertz Corp.* (2000) 78 Cal.App.4th 1144, 1166 (*Schnall*).) Since then, two of our sister courts have also agreed that *Cel-Tech's* "tethered" principle extends to consumer actions. In

Gregory v. Albertson's Inc. (2002) 104 Cal.App.4th 845 (*Gregory*), our colleagues in Division One of this District wrote: "*Cel-Tech*, however, may signal a narrower interpretation of the prohibition of unfair acts or practices in all unfair competition actions and provides reason for caution in relying on the broad language in earlier decisions that the court found to be 'too amorphous.' Moreover, where a claim of an unfair act or practice is predicated on public policy, we read *Cel-Tech* to require that the public policy which is a predicate to the action must be 'tethered' to specific constitutional, statutory or regulatory provisions." (*Id.* at p. 854, fn omitted.) In *Scripps Clinic*, Division One of the Fourth District agreed with the *Gregory* court's conclusion that *Cel-Tech* "narrowed the expansive earlier interpretations of the term 'unfair.'" (*Scripps Clinic, supra,* 108 Cal.App.4th at p. 940.)[8]

Furthermore, the UCL may not be used as a means of transferring to a court regulatory powers that have been legislatively bestowed on an agency. Case law illustrates that when regulatory systems are in place to deal with an issue, judicial intervention by means of the UCL may be neither necessary nor justified. (*Crusader Ins. Co. v. Scottsdale Ins. Co*. (1997) 54 Cal.App.4th 121, 138.).[9] Indeed, courts cannot "assume general regulatory powers" in order to resolve a claim brought under the UCL. (*Samura v. Kaiser Foundation Health Plan, Inc*. (1993) 17 Cal.App.4th 1284, 1301-1302, cert. denied (1994) 511 U.S. 1084 (*Samura*).)

3. *Analysis*

Applying these principles here, we hold that the trial court did not err by dismissing appellants' UCL claims. However, we affirm the trial court on somewhat

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[8] But see *Smith v. State Farm Mutual Automobile Ins. Co.* (2001) 93 Cal.App.4th 700, 720-721, footnote 23, where another appellate court declined to extend the "tethered" rationale of *Cel-Tech* to consumer actions.

[9] Our Supreme Court has "frequently noted the inappropriateness of judicial intervention in complex areas of economic policy." (*Harris v. Capital Growth Investors XIV* (1991) 52 Cal.3d 1142, 1168, fn 15; see also, to the same effect, *Quelimane Co. v. Stewart Title Guaranty Co.* (1998) 19 Cal.4th 26, 43; *Cel-Tech, supra,* 20 Cal.4th at p. 184.)

different bases than that articulated in its decision, the doctrine of judicial abstention. Rather, we do so on the bases that (1) under the undisputed facts developed during the summary judgment process, a court could not reasonably find the Guidelines to be unfair (or even unlawful under some common law theory or fraudulent) as *Cel-Tech* and subsequent UCL cases have interpreted those concepts, and (2) a court could not so hold without usurping regulatory powers that our Legislature has conferred on at least two agencies.

To elaborate on these reasons: First of all, and as our summary of the lower court proceeding suggests, appellants have not articulated any clear theories of liability to support their UCL claims. Indeed, the first amended complaint does not identify any predicate violation of a statute or other law. Eventually, appellants did attempt to articulate theories based on negligence, strict liability, and breach of fiduciary duty. Even if these theories were timely, which we seriously doubt, they are all premised on the assumption that tablet splitting is an unsafe practice and that the risks inherent in this practice are not justified by the fact that it saves costs. However appellants have failed to produce evidence to raise a triable issue of fact as to whether the Guidelines are, in fact, unsafe. As noted earlier, this record contains no evidence—nor even an allegation—that anyone has been harmed by Kaiser Permanente's Guidelines. Nor have we found any evidence to support appellants' contention that the Guidelines are unsafe. In this regard, we underscore two important points. First, both of appellants' experts characterize the Guidelines as "inappropriate and unwise," but not as unsafe. Second, appellants fault Kaiser Permanente for failing to adequately demonstrate that the Guidelines are safe but they have not shown, nor even alleged, that *they* can show the Guidelines are unsafe.

On the other hand, Kaiser Permanente has produced undisputed evidence to support the following facts: Tablet splitting for purposes of titration or when desired doses are unavailable is an acceptable practice in the health care industry. Further, tablet splitting for purposes of cost-saving is a common industry practice. Prescription drug costs, which have been steadily on the rise, are a significant component of healthcare

spending. Tablet splitting reduces the overall cost of a prescription drug benefit and thereby extends the value of the drug benefit to individual patients.

Therefore, when synthesized, the evidence before us shows that adopting tablet splitting policies in order to save costs is an industry-wide practice among managed health care providers and that there is no evidence that Kaiser Permanente's policy with respect to this practice has caused anyone actual physical injury or that it is demonstrably unsafe.

Moreover, the "tethered" language of *Cel-Tech* and the subsequent decisions in *Schnall*, *Gregory* and *Scripps Clinic* extending that principle to UCL consumer actions, leads us also to hold—as we did in *Schnall*—that any UCL action which is, as the present one, premised on "unfair practices" potentially impacting consumers must be "defined in connection with a legislatively declared policy . . . ." (*Schnall, supra,* 78 Cal.App.4th at p. 1166.) This action is clearly not so "defined" much less "tethered."[10] (See *Gregory, supra,* 104 Cal.App.4th at p. 854.)

This leaves only the "fallback" positions of appellants that the Guidelines are "unlawful" at common law, i.e., negligent or the like, and/or "fraudulent." But, as our Supreme Court has twice reminded us recently, a UCL action "'is not an all-purpose substitute for a tort or contract action.'" (*Korea Supply Co. v. Lockheed Martin Corp.* (2003) 29 Cal.4th 1134, 1150, quoting *Cortez v. Purolator Air Filtration Products Co.* (2000) 23 Cal.4th 163, 173.) The law is also clear that when a UCL claim is based on

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10 Appellants' only viable suggestions to the contrary are (1) a protestation that "Kaiser's protocol violates the spirit, if not the letter, of the FDA's regulatory scheme for assuring the safety and efficacy of prescription drugs" and (2) reliance—in the trial court, albeit not to us—on Civil Code section 3428. Neither argument has any merit. Regarding FDA regulations, that agency clearly did not think there was any violation of them because, as noted above, it flatly rejected a complaint of one of the appellants regarding Kaiser's pill splitting regimen. In any event, neither the trial nor appellate courts of this state are qualified to evaluate and apply, for section 17200 or any other purposes, the "spirit" of the FDA's regulations. As for Civil Code section 3428, that is clearly inapplicable here as, by its express terms, a requisite to liability thereunder is that the HMO "subscriber or enrollee suffered substantial harm." (Civ. Code, § 3428, subd. (a)(2).) As noted several times above, no such harm is alleged here.

some other law, a defense under that law is also a defense to the UCL claim. (See *Hobby Industry Assn. of America, Inc. v. Younger* (1980) 101 Cal.App.3d 358, 371; *People v. Duz-Mor Diagnostic Laboratory, Inc.* (1998) 68 Cal.App.4th 654, 673.) Since, of course, injury is an essential element of any tort claim (e.g., negligence, etc.: see Civ. Code, § 1714; 5 Witkin, Summary of Cal. Law (9th ed. 1988), Torts, § 3; Rest.2d, Torts, §§ 4, 7), the "unlawfulness" prong of appellants' argument fails because the absence of any alleged injury provides a complete defense to any such claim based on a common law tort theory.

Regarding the "fraud prong" of the UCL, appellants attempted to invoke this by alleging that Kaiser Permanente had made false and misleading statements about the quality of the medical care it provided. However, again, this theory is dependent upon a finding that the tablet splitting policy is unsafe and, as discussed above, no such evidence was produced to support this contention. Additionally, in a tentative ruling on the summary judgment motion, the trial court found that Kaiser Permanente made no affirmative misrepresentations concerning its pharmacy policies. Our review of the record supports this finding.

But appellants' UCL claims also fail for a second, separate and distinct reason: the Legislature has specifically established regulatory systems for the express purpose of overseeing the very type of activity complained of by appellants. Those systems have also been legislatively mandated to be the exclusive process by which practices in the health care industry can be challenged and regulated, except for narrow circumstances not present here. This was, indeed, the crux of the holding in *Samura, supra,* 17 Cal.App.4th at pages 1301-1302. In that case, a Kaiser Foundation Health Plan member filed an action against the Health Plan, the Permanente Medical Group and Kaiser Foundation Hospitals seeking injunctive relief under the UCL on behalf of himself and other similarly situated plan members. Plaintiff alleged, among other things, that a third party liability provision in the health plan agreement constituted an unfair business practice under the UCL because it violated several provisions of the Knox-Keene Health Care Service Plan Act of 1975, Health and Safety Code section 1340 et seq. (the Knox-

Keene Act). Although the trial court did not enjoin enforcement of the third party liability provision, it required Kaiser to make extensive changes to that provision in order to "'clarify and explain'" its terms. (*Samura, supra,* 17 Cal.App.4th at pp. 1289-1291.)

The *Samura* court reversed. It reasoned that the appellant's UCL claim could be based on acts that are made unlawful by the Knox-Keene Act, but not on provisions which pertained to the exercise of the Department's regulatory powers under the Act. The court then found that the challenged conduct was not made unlawful by any provision of the Act and that the trial court erred by finding a UCL violation based on Kaiser's failure to comply with "regulatory guidelines and requirements of the Knox Keene Act" which governed the exercise of the Department's regulatory powers under the Act. (*Samura, supra,* 17 Cal.App.4th. at p. 1301.) In an opinion written by now-retired Justice William Newsom, Division One of this District (the same court that decided *Gregory*) held that "[i]t is immaterial whether or not the challenged contract provisions and business practices comply with these portions of the Knox-Keene Act because the statutes do not define unlawful acts that may be enjoined under Business and Professions Code section 17200. In basing its order on these provisions, the trial court assumed a regulatory power over Health Plan that the Legislature has entrusted *exclusively* to the Department . . . ." (*Samura, supra,* 17 Cal.App.4th at pp. 1301-1302, emphasis added.)

Samura teaches that "courts cannot assume general regulatory powers over health maintenance organizations through the guise of enforcing Business and Professions Code section 17200. [Citation.]" (*Samura, supra*, 17 Cal.App.4th at pp. 1301-1302.) In the present case, appellants have not even alleged that Kaiser Permanente engaged in conduct made unlawful by the Knox-Keene Act nor by any other statute. Thus, they cannot show a UCL violation by establishing a substantive statutory violation.

Furthermore, appellants' UCL claims necessarily implicate the regulatory guidelines of not just the Knox-Keene Act but at least one other statute enacted by the Legislature for the express purpose of regulating the practices of health maintenance organizations like Kaiser Permanente.

Kaiser Permanente functions in what is clearly a heavily-regulated industry. As noted, Kaiser Foundation Health Plan, Inc., is licensed under the Knox-Keene Act. Under that statute, "the Department has broad authority to protect and promote the public interest in health plans." (*Van de Kamp v. Gumbiner* (1990) 221 Cal.App.3d 1260, 1284 (*Gumbiner*).) Additionally, to the extent Kaiser Permanente engages in the practice of pharmacy, Kaiser Permanente must comply with "The Pharmacy Law," a comprehensive statutory scheme that "regulates the dispensing of dangerous drugs, i.e., prescription medications." (*See Park Medical Pharmacy v. San Diego Orthopedic Associates Medical Group, Inc.* (2002) 99 Cal.App.4th 247; see also Bus. & Prof. Code, § 4000 et seq.)[11]

One court has characterized the net effect of these various statutes as manifesting a legislative intent to "occupy the field" of health care regulation. (*Gumbiner, supra,* 221 Cal.App.3d at p. 1284.) That court elaborated on this conclusion thusly: "The statutes governing the regulation and supervision of health plans represent a comprehensive system of licensing and regulation under the jurisdiction of the Department. . . . All aspects of the regulation of health plans are covered, including financial stability, organization, advertising and capability to provide health services." (*Ibid.*)

By erecting these statutory frameworks, our Legislature has created two regulatory bodies in which exclusive authority has been vested to grapple with the health care issues implicated by this case. The Department of Managed Care was established pursuant to the Knox-Keene Act and is responsible for executing state laws relating to health services plans and the health service plan business including, in particular, laws charging the Department with the responsibility to "ensure that health care service plans provide enrollees with access to quality health care services and protect and promote the

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11 Kaiser Permanente is also qualified under the federal Health Maintenance Organization Act of 1973, 42 United States Code section 300e et seq. (See *Samura, supra,* 17 Cal.App.4th at p. 1289.)

interests of enrollees." (Health & Saf. Code, § 1341, subd. (a).)[12] As the *Samura* court noted, section 1342 of the Knox-Keene Act, which contains a statement of legislative purpose, is an example of a provision governing the Department in the exercise of its regulatory powers. (*Samura, supra*, 17 Cal.App.4th at p. 1301.) Pursuant to section 1342.6, the Department is charged with "ensur[ing] that the citizens of this state receive high-quality health care coverage in the most efficient and cost-effective manner possible." Its responsibilities also include "controlling costs and improving quality and access to care" (Health & Saf. Code, § 1342.1, subd.(b)(2)), and "ensur[ing] the best possible health care for the public at the lowest possible cost . . ." (Health & Saf. Code, § 1342, subd. (d).)

The Board of Pharmacy administers the Pharmacy Law and performs licensing, regulatory and disciplinary functions in order to meet its "highest priority" which is "the protection of the public." (Bus. & Prof. Code, § 4001.1.) The Board is expressly authorized to adopt "rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public." (Bus. & Prof. Code, § 4005, subd. (a).)

Both the Department of Managed Care and the Board of Pharmacy have initiated investigations regarding Kaiser Permanente's tablet splitting policies. Appellants do not contend that either is unqualified or ill-equipped to make a policy determination as to whether or under what circumstances tablet splitting can properly be used as a cost saving tool. Nor have they articulated any justification for judicial interference with these investigations. Indeed, in light of the provisions of the Knox-Keene Act and the

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[12] The Director of the Department has extensive powers not just to administer and enforce the provisions of the Knox-Keene Act, but also to provide information to and otherwise assist federal and state legislative committees and agencies in order to protect and promote the interests of plans, subscribers, enrollees and the public. (Health & Saf. Code, § 1346.) The Director is also expressly empowered to study, investigate, research and analyze matters affecting these interests and to hold public hearings, subpoena witnesses, take testimony, and compel the production of evidence in order to implement the purposes and enforce the provisions of the Knox-Keene Act. (*Id*. at § 1346, subd. (a)(4)-(5).)

Pharmacy Law which govern the exercise of theses agencies' regulatory powers, we cannot conceive of how a court could find a UCL violation in this case without improperly assuming a regulatory function that the Legislature has assigned exclusively to the Department of Managed Care and/or the Pharmacy Board.

Appellants' basic position is that potential risks inherent in the practice of tablet-splitting are acceptable in some contexts but make this practice unfair and unlawful when tablets are split in order to reduce medical costs. The healthcare policy concerns raised by this claim directly implicate the regulatory functions of the two agencies the Legislature has established to oversee the practices of managed care providers like Kaiser Permanente. By contrast, and as the United States Supreme Court has expressly cautioned, the judicial branch should not precipitously intrude into the complex and thoroughly-regulated health care industry without compelling reasons for doing so. (*Pegram v. Herdrich* (2000) 530 U.S. 211 (*Pegram*).)

Appellants contend that *Samura, supra*, 17 Cal.App.4th 1284 and other cases acknowledging limits on the scope of the UCL are distinguishable on the ground that the present case raises issues relating to personal injury, health and safety which a court can and should resolve in the first instance. We repeat and underscore that there is no evidence, nor even an allegation, in this case that the challenged practice has caused anyone actual physical harm. Thus, the health and safety issues raised by appellants claims are *necessarily* issues which directly implicate the regulatory powers and functions of the Department of Managed Care and the Pharmacy Board.

Under these circumstances, and for both of the reasons set forth above, we hold that the trial court did not err in dismissing appellants' UCL claims.

B. ***The Arbitration Order***

As noted in our factual summary, the trial court found that the claim for damages under the CLRA was subject to arbitration, severed that claim and stayed the arbitration pending resolution of the equitable claims. Prior to this appeal, appellants filed a writ in this court challenging the trial court's order compelling arbitration. After reviewing briefs from the parties, this court summarily denied appellants' writ. In this case,

appellants renew their challenge to the arbitration order. Kaiser Permanente maintains the order is not appealable and that, in any event, the order is proper.

The appealability of orders and judgments rendered in judicial proceedings to enforce arbitration agreements is governed by section 1294 of the Code of Civil Procedure which provides: "An aggrieved party may appeal from: [¶] (a) An order dismissing or denying a petition to compel arbitration. [¶] (b) An order dismissing a petition to confirm, correct, or vacate an award. [¶] (c) An order vacating an award unless a rehearing in arbitration is ordered. [¶] (d) A judgment entered pursuant to this title. [¶] (e) A special order after final judgment." "'[A]n order directing arbitration, not being one of those orders listed in section 1294 . . . , is not appealable.' [Citation.]" (*Muao v. Grosvenor Properties, Ltd*. (2002) 99 Cal.App.4th 1085, 1088 (*Muao*).)

An order compelling arbitration is reviewable on appeal from a judgment entered after the arbitration is completed or, in exceptional circumstances, by writ of mandate. (*Muao, supra,* 99 Cal.App.4th at p. 1088; *Mid-Wilshire Associates v. O'Leary* (1992) 7 Cal.App.4th 1450, 1454.) "The rationale of this rule is that an order compelling arbitration is interlocutory in nature and works no hardship on the litigant because the party who objects to arbitration may win at the arbitration hearing, and if he does not, the issue is reviewable on appeal from the order of confirmation." (*Spence v. Omnibus Industries* (1975) 44 Cal.App.3d 970, 976.)

Appellants acknowledge this general rule but contend it does not apply here because a final judgment has been entered and the arbitration order is reviewable as an interim interlocutory order pursuant to Code of Civil Procedure section 906 (section 906). This argument is inconsistent with *Muao, supra*, 99 Cal.App.4th 1085, a case decided by a panel of Division Three of this court which appellants overlook.

The *Muao* appellant attempted to appeal from an order compelling arbitration after the trial court dismissed his wrongful termination action against his employer. (*Muao, supra,* 99 Cal.App.4th 1085.) Like appellants here, the *Muao* appellant argued the order was an intermediate order appealable pursuant to section 906. The *Muao* court disagreed reasoning that section 906 authorizes a reviewing court to review "only an

'intermediate . . . order . . . which involves the merits or necessarily affects the judgment . . . appealed from or which substantially affects the rights of a party. . . .'" (*Id*. at p. 1089, quoting § 906.) Thus, the court found, the order compelling arbitration was not subject to review because it did not affect the merits of appellant's claims, or the judgment and it did not substantially affect appellant's rights. As to this last point, the court noted that appellant could prevail at the arbitration proceeding and, if he did not, he could then challenge the order compelling arbitration on appeal from any judgment entered on the arbitration award. *(Ibid; see also Laufman v. Hall-Mack Co*. (1963) 215 Cal.App.2d 87, 88-90.)

We agree with the *Muao* court's analysis of this issue and follow it here. Therefore, the order compelling arbitration of appellants' damages claim is not appealable at this time.

IV. DISPOSITION

The appeal from the order compelling arbitration is dismissed as premature. The judgment is otherwise affirmed.

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Haerle, Acting P.J.

We concur:

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Lambden, J.

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Ruvolo, J.